

Attorney Docket No.: **KUZ-0021**
Inventors: **Suzuki et al.**
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REMARKS

At the outset, Applicants thank Examiner Palenik for his time and consideration of a further interview and for his further clarification of reasoning behind citation of the Tomaru reference.

Claims 3-14 and 16 are pending in the instant application. Claims 3-14 and 16 have been rejected. Claim 13 has been amended. Claims 6 and 7 have been canceled in light of the amendments to claim 13. New claims 17 and 18 have been added. Support for the amendment to claim 13 is provided by canceled claims 6 and 7. Support for claims 17 and 18 is provided in the examples of specification beginning at page 22 and in particular in Tables 1 and 2 at pages 27 and 28, respectively. No new matter has been added by these amendments and entry is respectfully requested. Reconsideration is respectfully requested in light of these amendments and the following remarks.

Rejection of Claims under 35 U.S.C. 103(a)

The rejection of claims 13, 5, 9, 10 and 14 under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Chono et al. (U.S. Patent No. 6,139,866) and

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Tomaru et al. (U.S. Patent No. 6,563,195) has been maintained.

The rejection of claims 3, 4, 6-9, 11 and 12 under 35 U.S.C. 103(a) as being unpatentable over Chono et al. with respect to claim 13 as set forth above has also been maintained.

In addition, claim 16 has been rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Chono et al. and Tomaru et al. as set forth above with respect to claim 13 in combination with Nakahara et al. (provided as an English machine translation of JP 06-287134).

Applicants respectfully traverse these rejections.

The Examiner suggested via telephone on February 17, 2010 that Tomaru is cited for its teachings of the property that the film can be roughened to enhance its adherence and that citation of this reference for this purpose is proper.

It is respectfully pointed out, however, that Tomaru teaches a range of 0.1 to 5.0 μm , preferably 0.3 to 2.0 μm surface roughness (Ra) for their covering sheet. See col. 3, lines 30-32. Tomaru et al. teaches away from an Ra lower than 0.1 μm because when the Ra is smaller than 0.1 μm , the silicone rubber tends to fall out and undergo displacement during the production working and the dustproof covering

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film tends to peel off and slide during transport and the installation working, and thereby particles are formed. See col. 3, lines 40-44.

In contrast, claim 13 recites the limitation that said polyester-based film surface in contact with said drug-containing adhesive has a surface roughness (Ra) of from 0.05 to 0.8 μm . New claims 17 and 18 have been added which recite the further limitation that said polyester-based film surface in contact with said drug-containing adhesive has a surface roughness (Ra) of from 0.1 to 0.6 μm or from 0.1 to 0.3 μm , respectively. As evidenced by the Examples set forth beginning at page 22 of the instant application, this range of surface roughness is critical to the anchoring properties (see Table 1 at page 27) and an absence of pinholes (see Table 2 at page 28).

As evidenced by Table 1, a surface roughness below the claimed range exhibited anchoring collapse between the substrate and the adhesive layer. See comparative example 1-1. Anchoring collapse is described at pages 26-27 of the patent application as "detachment between the substrate and the adhesive layer."

As evidenced by Table 2, roughening the surface of the film above the claimed range created pinholes in the film. See comparative examples 2.1, 2.2, 3.1 and 3.2. It is well

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established in this art field that the presence of pinholes produces multiple problems. In particular, when a solution containing drug and adhesive is applied to a support with pinholes, the solution permeates through the pinholes reaching the backside of the support. This results in drug and adhesive contamination for the subject to which the patch is applied as well as unwanted exposure to the drug by a practitioner applying the patch and those who produce and supply the patch. Permeation of drug and adhesive through pinholes in the support also soils the production devices, thus obstructing normal production of the patch. The presence of pinholes also results in a patch which does not exhibit its desired therapeutic effect since the adhesive matrix cannot be uniform. Storage of patches with pinholes in the substrate is also problematic as seepage of drug through the pinholes during storage reduces drug retention and stability of the patch. The presence of pinholes also reduces strength of the support causing difficulties in production and peeling of the patch from the skin.

MPEP 2144.05 is clear; a *prima facie* case of obviousness based on overlapping ranges can be rebutted by showing the criticality of the claimed range. "The law is replete with cases in which the difference between the claimed

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invention and the prior art is some range or other variable within the claims. . . . In such a situation, the applicant must show that the particular range is critical, generally by showing that the claimed range achieves unexpected results relative to the prior art range." *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990).

The claimed ranges of surface roughness (Ra) of 0.05 to 0.8 μm , 0.1 to 0.6 μm or 0.1 to 0.3 μm of the instant invention demonstrated to be critical to:

(1) anchoring between the polyester-based film and a drug containing adhesive layer containing styrene-isoprene-styrene block copolymer or polyisobutylene and styrene-isoprene-styrene block copolymer; and

(2) inhibition of formation of pinholes in the polyester-based film,

are clearly unexpected relative to the 0.1 to 5.0 μm range and the preferred 0.3 to 2.0 μm range taught by Tomaru et al. to be required for a peel strength of 5 to 500 g/25 mm of a dust cover film from a silicone rubber layer. Tomaru et al. expressly teaches away from use of a surface roughness below 0.1 μm . Further, the breadth of the disclosed range of Tomaru et al. extends well-above the instant claimed range demonstrated to be critical to

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avoidance of pinholes. In fact, Applicants believe Tomaru's focus on eventual peelability of a dust cover film away from the silicone rubber layer provides no expectation whatsoever with respect to the instant claimed invention wherein anchoring without detachment and no pinholes are the objective.

The Examiner implies at page 4 of the Office Action that the limitation in the claims of the PET film layer being without pinholes is taught by Chono et al. by the silence of this reference with respect to the presence of pinholes. Clear from data presented at page 28 of the instant application is that pinholes in the film layer are created by roughening the film surface to a surface roughness of 1.0 μm or greater, a step which is not taught in any way by Chono et al. (or Nakahara et al.) but which falls well within the surface roughness range of 0.1 to 5.0 μm as well as the preferred surface roughness range of 0.3 to 2.0 μm expressly taught by Tomaru et al.

Thus, the demonstrated criticality of the claimed range of the instant invention in providing desired anchoring properties with no detachment of the polyester based film from the adhesive while producing no undesired pinholes, neither of which are objectives of Tomaru et al., clearly rebuts any *prima facie* case of obviousness over this

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reference when combined with Chono et al., acknowledged by the Examiner not to teach PET film having a surface roughness ranging from 0.05 to 0.8 μm , and/or Nakahara et al. which also does not teach or suggest PET film having a surface roughness ranging from 0.05 to 0.8 μm .

Applicants further respectfully disagree with the citation of Tomaru et al. in combination Chono et al. and/or Nakahara et al. as establishing any *prima facie* case of obviousness.

MPEP 2141.01(a) entitled Analogous and Nonanalogous Art states: to rely on a reference under 35 U.S.C. 103, it must be analogous prior art. The Examiner must determine what is "analogous prior art" for the purpose of analyzing the obviousness of the subject matter at issue. "Under the correct analysis, any need or problem known in the field of endeavor at the time of the invention and addressed by the patent [or application at issue] can provide a reason for combining the elements in the manner claimed." *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1397 (2007). The Court in KSR suggested that a reference in a field different from that of applicant's endeavor **may be** reasonably pertinent. Case law and the MPEP make clear, however, that a reference is **only** analogous if

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it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his or her invention as a whole.

Repeatedly, the courts have looked to the similarities and differences in structure and function of the inventions, as well as similarities in the problem to be solved to determine if the references are analogous. For example, in *In re Ellis*, 476 F.2d 1370, 1372, 177 USPQ 526, 527 (CCPA 1973), the structural similarities and functional overlap between the structural gratings shown by one reference and the shoe scrapers of the type shown by another reference were determined to be readily apparent, and therefore the arts to which the reference patents belonged were reasonably pertinent to the art with which appellant's invention dealt (pedestrian floor gratings). In *Ex parte Bland*, 3 USPQ2d 1103 (Bd. Pat App. & Inter. 1986), the claims were drawn to a particulate composition useful as a preservative for an animal foodstuff (or a method of inhibiting fungus growth in an animal foodstuff therewith) comprising verxite having absorbed thereon propionic acid. All references were concerned with absorbing biologically active materials on carriers, and therefore the Board held the teachings in each of the various references would have been pertinent to the

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problems of the invention at hand. In *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983), the problem confronting the inventor was preventing electrostatic buildup in PTFE tubing caused by hydrocarbon fuel flow while precluding leakage of fuel. Two prior art references relied upon were in the rubber hose art, both referencing the problem of electrostatic buildup caused by fuel flow. The court found that because PTFE and rubber are used by the same hose manufacturers and experience the same and similar problems, a solution found for a problem experienced with either PTFE or rubber hosing would be looked to when facing a problem with the other. In *In re Mlot-Fijalkowski*, 676 F.2d 666, 213 USPQ 713 (CCPA 1982), the problem faced by appellant was enhancement and immobilization of dye penetrant indications. References which taught the use of dyes and finely divided developer materials to produce colored images preferably in, but not limited to, the duplicating paper art were properly relied upon because the court found that appellant's problem was one of dye chemistry, and a search for its solution would include the dye arts in general. In *Stevenson v. International Trade Comm.*, 612 F.2d 546, 550, 204 USPQ 276, 280 (CCPA 1979), the Court held that for simple mechanical

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inventions it is reasonable to permit inquiry into other areas where one of ordinary skill in the art would be aware that similar problems exist. Thus, in *In re Bigio*, 381 F.3d 1320, 1325-26, 72 USPQ2d 1209, 1211-12 (Fed. Cir. 2004), the CAFC determined art on toothbrushes to be analogous to hair brushes because toothbrushes are structurally similar to small brushes for hair, and a toothbrush could be used to brush facial hair. 381 F.3d at 1326, 72 USPQ2d at 1212. In *Pentec, Inc. v. Graphic Controls Corp.*, 776 F.2d 309, 227 USPQ 766 (Fed. Cir. 1985), the CAFC held that the problem confronting the inventor was the need for a simple holding means to enable frequent, secure attachment and easy removal of a marker pen to and from a pen arm, and one skilled in the pen art trying to solve that problem would have looked to the fastener and hinge art. In *Ex parte Goodyear Tire & Rubber Co.*, 230 USPQ 357 (Bd. Pat. App. & Inter. 1985), the Board held that a reference in the clutch art was held reasonably pertinent to the friction problem faced by applicant, whose claims were directed to a braking material, because brakes and clutches utilize interfacing materials to accomplish their respective purposes. In *Medtronic, Inc. v. Cardiac Pacemakers*, 721 F.2d 1563, 220 USPQ 97 (Fed. Cir. 1983), the CAFC held that one of ordinary skill in the

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pacemaker designer art faced with a rate-limiting problem would look to the solutions of others faced with rate limiting problems, and therefore the references were in an analogous art. Finally in a recent Board decision *Ex parte ROBERT C. DART, RYAN P. GINGRAS and TOOD ATKINS* Appeal 2007-1325 Application 101065,722 Technology Center 3781, the Board considered several cited art references to be analogous art because each was reasonably pertinent to the problem with which the inventor was concerned.

In each of the above cases, the Courts compared the similarity of the problem being solved by the claimed invention and the cited art reference and/or structural similarities between the claimed invention and the cited art reference to determine whether or not the cited art was analogous as required by MPEP 2141.01(a).

Tomaru et al. shares neither similarity of the problem being solved by the claimed invention nor structural similarities.

At page 6 of the instant patent application it is stated that "the object of the invention is to solve the problems of the prior arts . . . to provide a patch which is free of any migration of drug into a substrate and shows favorable anchoring properties between the substrate and an

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adhesive layer, in which the drug containing adhesive layer is firmly adhered onto the substrate and which remains no adhesive residue when applied to the skin and then peeled off." Further at page 6 of the instant application it is disclosed that "the inventors surprisingly found out that the anchoring properties between a substrate and an adhesive layer is improved by using a polyester-based film having the surface roughness of a specially fixed value" Favorable anchoring properties are described at page 2 of the instant application as "firm adhesion between the substrate and the adhesive and no adhesive residue when peeled off from the skin."

In contrast, Tomaru et al. expressly states that their invention resolves the "problem that particles adhere to the front and/or rear surface of a [semiconductor] wafer in the production process" (see col. 1, lines 19-24 of Tomaru et al.) by "providing a special dustproof covering film on the silicon rubber surface of a wafer support of the type which has the silicone rubber layer on a base made of ceramic and/or metal and peeling the dustproof covering film apart from the silicone rubber layer immediately before use" (see col. 1, line 61 through col. 2, line 2).

The problem of preventing particles from adhering to a semiconductor wafer surface and the solution of providing a

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dustproof covering film which peels apart from the silicon rubber surface of a wafer support are in no way similar to the problem of improving anchoring properties of firm adhesion between a substrate and an adhesive layer of a transdermal drug delivery patch so that no adhesive residue remains when the patch is peeled off from the skin. In fact, the solution of Tomaru et al. of a dustcovering film which peels away from the device upon use is actually opposite to the problem to solved in the instant invention of a patch with a substrate and drug-containing adhesive layer firmly adhered so that upon peeling of the patch from the skin, the drug-containing adhesive layer remains adhered to the substrate and not to the skin.

The structure and function of the invention of Tomaru et al. is also completely different from the instant invention.

Tomaru et al. relates to a wafer support used for fixing a semiconductor wafer used in personal computers, game machines and cellular phones. More specifically, as taught at col. 1, lines 61 through col. 2, line 16 of Tomaru et al., the invention is a dustproof covering film-attached wafer support comprising a base made of ceramic or metal, a silicone rubber layer substantially uniform in thickness and integrated with the base and a dustproof covering film,

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wherein the covering film is attached to the silicone rubber layer in a state that the covering film is capable of being peeled apart from the silicone rubber layer and the peel strength between the covering film and the silicone rubber layer is from 5 to 500 g/25 mm, measured by the peeling test according to JIS K 6854.

In contrast, claim 13 of the instant application is drawn to a patch comprising a substrate made of a polyester-based film and a drug-containing adhesive layer laminated thereon, wherein a side of said polyester-based film surface in contact with said drug-containing adhesive has a surface roughness (Ra) of from 0.05 to 0.8 μm thereby increasing anchoring between said polyester-based film. Clear from teachings of the specification is that the function of the patch is as a percutaneous absorption preparation to deliver a drug to a patient via adherence of the patch to the skin of the patient. In an earnest effort to further distinguish the structure of the present invention from Tomaru et al., Applicants have further amended claim 13 to recite that the drug-containing adhesive layer contains styrene-isoprene-styrene block copolymer or polyisobutylene and styrene-isoprene-styrene block copolymer. Support for this amendment is provided by dependent claims 6 and 7, now canceled.

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Thus, the semiconductor wafer of Tomaru et al. clearly does not contain the claimed structural element of the instant claimed patch of a drug-containing adhesive layer containing styrene-isoprene-styrene block copolymer or polyisobutylene and styrene-isoprene-styrene block copolymer. Nor does the semiconductor wafer of Tomaru et al. contain the claimed structural element of the instant claimed patch of a polyester-based film laminated on the drug-containing adhesive layer. Further, the instant claimed patch clearly does not contain the structural elements of a ceramic or metal base, a silicon rubber layer, or a peelable dustproof covering film of Tomaru et al.

Thus, since Tomaru et al. shares neither similarity of the problem being solved by the claimed invention nor structural similarities, it is not analogous prior art and therefore it cannot be relied upon as a reference under 35 U.S.C. 103. MPEP 2141.01(a). The rejection of claims 13, 5, 9, 10 and 14 under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Chono et al. (U.S. Patent No. 6,139,866) and Tomaru et al. (U.S. Patent No. 6,563,195) is therefore improper and must be withdrawn.

Further improper is maintenance of the rejection of dependent claims 3, 4, 6-9, 11 and 12 under 35 U.S.C. 103(a) as being unpatentable over Chono et al. alone. MPEP 2143.03

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and case law of *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) state: "if an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious." As claims dependent from claim 13, claims 3, 4, 6-9, 11 and 12 require all elements of claim 13 including a side of said polyester-based film surface in contact with said drug-containing adhesive having a surface roughness (Ra) of from 0.05 to 0.8 μm thereby increasing anchoring between said polyester-based film. However, the Examiner has expressly acknowledged in the prosecution history that the surface roughness is a structural limitation of the polyester-based film not addressed by Chono et al. See pages 3-4 of the Office Action mailed May 11, 2009.

There is also no teaching or suggestion in Nakahara et al. of the claim limitation of a side of said polyester-based film surface in contact with said drug-containing adhesive having a surface roughness (Ra) of from 0.05 to 0.8 μm .

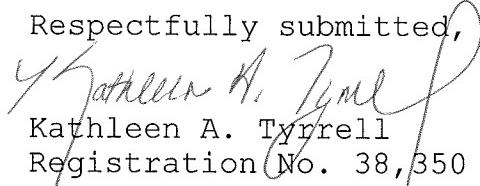
Accordingly, as the cited combinations of analogous art with respect to the instant claimed invention do not teach or suggest all limitations of the instant claimed invention, they cannot render obvious the instant claimed invention.

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Withdrawal of all rejections under 35 U.S.C. 103(a) is respectfully requested.

Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

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